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Two recent Federal Circuit rulings provide some clarity on the availability of patent term extensions for drug patents, but they leave questions about the scope of the rights conferred.

The Impact of Recent Federal Circuit Decisions on Patent Term Extension

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The U.S. Court of Appeals for the Federal Circuit recently decided two cases, *PhotoCure ASA v. Kappos*, No. 2009-1393 (Fed. Cir. May 10, 2010) (80 PTCJ 56, 5/14/10), and *Ortho-McNeil Pharmaceutical Inc. v. Lupin Pharmaceuticals Inc.*, No. 2009-1362 (Fed. Cir. May 10, 2010) (80 PTCJ 55, 5/14/10), regarding the availability of patent term extension.

Under certain conditions, patent term extension restores patent term lost by Food and Drug Administration review. While these decisions have some clear effects, they also create uncertainty, particularly with respect to the scope of protection conferred by patent term extension.

A. *Photocure* and *Ortho-McNeil*

The patent term extension statute, 35 U.S.C. § 156, defines ''product'' as a ''drug product,'' which is further defined as ''the active ingredient of a new drug . . . in-

cluding any salt or ester of the active ingredient.''[1] Thus, Section 156 defines ''product'' as the ''active ingredient'' and any ''salt'' or ''ester'' of the ''active ingredient.''

The most important aspect of *Photocure* and *Ortho-McNeil* was the meaning of ''product,'' as used in Section 156. Prior to *Photocure* and *Ortho-McNeil*, there were two competing views of the statute: (1) a plain meaning construction; and (2) an ''active moiety'' construction, which was the Patent and Trademark Office's view of the statute.

The Federal Circuit first employed a plain meaning construction in *Glaxo Operations U.K. Ltd. v. Quigg*, 894 F.2d 392, 13 USPQ2d 1628 (Fed. Cir. 1990) (39 PTCJ 242, 2/1/90), by looking literally at the drug's active ingredient. A later Federal Circuit decision that did not cite *Glaxo*, however, employed an active moiety construction.[2] *Pfizer* looked at the biologically active species, i.e., the ''active moiety,'' of the active ingredient.

Photocure and *Ortho-McNeil*, which both considered patent term extension eligibility, resolved this dispute in favor of plain meaning when applying Section 156. In *Photocure*, the Federal Circuit considered the PTO's refusal to extend a patent covering methyl aminolevulinate hydryochloride (''MAL hydrochloride'') in view of prior approval of another drug, aminolevulinic acid hydrochloride (''ALA hydrochloride'').[3]

MAL hydrochloride and ALA hydrochloride share the same parent acid, aminolevulinic acid (''ALA'').[4] The PTO refused the extension because in its view, ''the underlying molecule, or active moiety, [of a drug] and all of its salts and esters qualify as the same 'product.' ''[5]

The Federal Circuit rejected the PTO's position as an ''incorrect statutory interpretation'' and held that the plain meaning construction of the statute, as applied in *Glaxo*, was proper.[6] *Ortho-McNeil* confirmed this construction of ''active ingredient.''[7]

Ortho-McNeil specifically considered the issue of whether approval of a drug with an enantiomer active ingredient was a first permitted commercial marketing or use in view of prior approval of a drug with the enantiomer's racemate as its active ingredient.[8]

The Federal Circuit held that approval of the enantiomer drug constituted the first permitted commercial marketing or use for purposes of Section 156.[9] The court noted that the PTO and FDA had a longstanding and consistent policy of considering enantiomeric active ingredients as separate from their racemates.[10] Thus, approval of the enantiomer drug product merited patent term extension despite prior approval of the racemate drug product.

Both *Photocure* and *Ortho-McNeil* noted that the active ingredients at issue were separately patentable over the previously approved active ingredients. In *Photocure*, for example, the court noted that ''even on the PTO's incorrect statutory interpretation MAL would meet the criteria for term extension, for, as the '267 patent illustrates, the pharmacological properties of MAL differ from those of ALA, *supporting the separate patentability* of the MAL product.''[11]

Photocure also distinguished *Pfizer* by noting that ''*Pfizer* did not hold that extension is not available when an existing product is substantively changed in a way that produces a new and separately patentable product having improved properties and requiring full FDA approval.''[12] Similarly, *Ortho-McNeil* referenced the ''separate patentability'' of the enantiomer at issue.[13] This is interesting because patentability does not appear in Section 156 as a factor determining eligibility for patent term extension.

B. Fallout From *Photocure* and *Ortho-McNeil*

Two effects from *Photocure* and *Ortho-McNeil* are fairly clear. First, ''active ingredient,'' as used in Section 156, means the actual active ingredient of the drug as opposed to the ''active moiety'' of the active ingredient, at least in terms of patent eligibility.

This opens the door for pharmaceutical companies to obtain patent term extension on follow-on or improvements to drugs that have previously benefitted from patent term extension. Specifically, the PTO's operative construction of ''active ingredient'' prior to *Photocure* and *Ortho-McNeil* foreclosed the possibility of patent term extension when a previously approved drug shared the same ''active moiety.''

Now that the Federal Circuit has rejected this construction, patentees can obtain extensions for drugs even when a previously approved drug shares a common ''active moiety.'' Thus, a net effect of *Photocure* and *Ortho-McNeil* should be an increase in the availability of patent term extension.

Second, in most if not all cases, approval of enantiomer drug products will form the basis for patent term extension when a racemate drug product was previously approved, assuming the other eligibility criteria are met. This practice is consistent with FDA and PTO policy. Indeed, ''in each and every instance in which it has considered the question, the FDA has described a racemate as a single active ingredient, distinct from its enantiomers, and each enantiomer as a single active ingredient distinct from the other and from the racemate.''[14]

Because *Ortho-McNeil* confirms existing FDA and PTO practice, it will likely have little effect at the agency level. But it will discourage, if not foreclose, generic competitors from challenging patent term extensions based on enantiomer approval as improperly granted, which was the precise situation addressed by *Ortho-McNeil*.

Photocure and *Ortho-McNeil*, however, leave unclear the role that ''separate patentability'' plays in patent term extension. *Photocure* and *Ortho-McNeil* both men-

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[1] 35 U.S.C. § 156(f)(1) and (2).

[2] *Pfizer Inc. v. Dr. Reddy's Laboratories Ltd.*, 359 F.3d 1361, 69 USPQ2d 2016 (Fed. Cir. 2004) (67 PTCJ 395, 3/5/04).

[3] *Photocure*, slip. op. at 3-4.

[4] *Id*.

[5] *Id.* at 4 (internal citations omitted).

[6] *Id.* at 5.

[7] *Ortho-McNeil*, slip op. at 6 (''The FDA and PTO practices are in accordance with *Glaxo*, where the court held that 'product' as used in § 156(a) is the active ingredient present in the drug.'').

[8] *Ortho-McNeil*, slip op. at 5.

[9] *Id.* at 6.

[10] *Id*.

[11] *Photocure*, slip. op. at 5 (emphasis supplied).

[12] *Id.* at 6 (emphasis supplied).

[13] *Ortho-McNeil*, slip op. at 6.

[14] *Ortho-McNeil*, slip op. at 6 (quoting expert declaration, citations to record omitted).

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tion separate patentability of the active ingredient at issue as a factor supporting grant of patent term extension, as discussed above.

Indeed, *Photocure* suggests that separate patentability may be a dispositive factor by noting that ''even on the PTO's incorrect statutory interpretation MAL would meet the criteria for term extension, for, as the '267 patent illustrates, the pharmacological properties of MAL differ from those of ALA, *supporting the separate patentability* of the MAL product.''[15] Yet Section 156(a), which defines the criteria for patent term extension eligibility, makes absolutely no mention of patentability. And *Photocure* and *Ortho-McNeil* do not clearly define the role of separate patentability in the analysis.

The role of separate patentability may be important in two cases. The first case is where extension is sought based on a drug with an active ingredient different from the active ingredient of a previously approved, but where the active ingredient is *not* separately patentable. In other words, the approval is indeed the first according to the plain meaning of the statute, but separate patentability does not exist.

This may become an issue where, for example, an enantiomer is not separately patentable over its racemate. It could be argued that the *Photocure* and *Ortho-McNeil* require separate patentability to distinguish a previously approved drug product. A patentee faced with this argument would likely reply that Section 156 does not require separate patentability, so the lack of separate patentability cannot be a basis for denying patent term extension. Because *Photocure* and *Ortho-McNeil* do not clearly define the role of patentability, how the Federal Circuit would resolve this argument remains unclear.

The second case is where an active ingredient is not different from a previously approved active ingredient based on a plain meaning of Section 156, but the active ingredient is separately patentable. This may be the case where, for example, the active ingredient for which extension is sought is a salt or ester of a previously approved active ingredient.[16]

A patentee could argue based on *Photocure* and *Ortho-McNeil* that the separate patentability alone means that the active ingredient is different from the previously approved active ingredient. This argument would be bolstered considerably if full FDA approval was required because *Photocure* and *Ortho-McNeil*, as well as *Pfizer*, considered whether separate FDA approval was required.

The PTO, or a party challenging the propriety of a granted extension, could respond that Section 156 makes no mention of patentability. Thus, relying on separate patentability contravenes the requirements set by statute. The party challenging patent term extension appears to have the upper hand in this argument, but *Photocure* and *Ortho-McNeil* do not provide a clear answer.

Although *Photocure* and *Ortho-McNeil* consider patent term extension in the context of eligibility, the decisions will likely impact the scope of protection conferred by a patent term extension. The scope of protection available during the extended term of a patent claiming a ''product'' is limited to the ''product'' for approved uses of the ''product,'' as opposed to the entire claim scope. And ''product'' is defined identically for both eligibility for patent term extension and rights conferred during the extended term.

Thus, ''product'' seemingly should have identical meanings in the context of both patent term extension eligibility and scope of protection conferred. This means that scope of protection narrows as eligibility becomes more lax as a general rule.

If ''product'' is applied identically in both eligibility and scope of protection determinations, *Photocure* and *Ortho-McNeil* may be viewed as narrowing protection during extended term. Specifically, a competitor could potentially avoid an extended patent's scope by using a different salt or ester even if the different salt or ester shares an ''active moiety'' with the drug that formed the basis for patent term extension.

But *Pfizer* held that a patent extended based on approval of a salt of a drug covered a *different* salt. This result is arguably not consistent with a plain meaning application of Section 156.

Confronted with this situation, a patentee could argue, for example, that *Pfizer*, rather than *Photocure* and *Ortho-McNeil*, is controlling in the context of enforcement because *Photocure* and *Ortho-McNeil* considered only eligibility for patent term extension. This argument would be strengthened if the allegedly infringing product had activity similar to the existing product and/or was not separately patentable.[17]

Nonetheless, this argument would be difficult to press given that identical statutory language is used in Section 156 to define both the eligibility for patent term extension and rights conferred during the extended term. An accused infringer, on the other hand, would likely argue that *Glaxo*, *Photocure*, and *Ortho-McNeil* control and that *Pfizer* is limited to its facts.

Specifically, the infringer in *Pfizer* was able to rely on the data that the patentee submitted to the FDA for approval of its drug. And it appears that the infringing drug was not improved as compared to the existing drug or separately patentable.[18]

While *Photocure* and *Ortho-McNeil* provided substantial clarity with respect to patent term extension eligibility, questions remain, especially in terms of the scope of rights conferred by patent term extension. These questions stem, in large part, from the Federal Circuit's reliance on factors not enumerated in the controlling statute, 35 U.S.C. § 156.

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[15] *Photocure*, slip. op. at 5 (emphasis supplied).

[16] *See* 35 U.S.C. § 156(f)(2) (defining ''drug product'' as ''the active ingredient . . . including any salt or ester of the active ingredient'').

[17] *Photocure*, slip. op. at 6.

[18] *See Photocure*, slip. op. at 6.

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